

REMARKS / ARGUMENTS

Claims 1, 17, 23, 30, 33, 40 and 50 are currently amended.

Claims 4 and 25 are cancelled by the current amendment.

Claims 51, 52 and 53 are newly added.

Thus claims 1-3, 5-24, 26-30, 32-34, 36-38, 40, 41, and 43-53 are currently pending.

Independent claims 1, 23 and 30 are herein amended by incorporating therein the subject matter of previous claims 4 and 25 (now cancelled). Therefore, these claims newly recite that a level of positive pressure applied to the patient's lungs is adjusted as a function of the neural inspiratory activation. Support for these amendments is found in the disclosure as originally filed, for example with original claims 4 and 25 and at paragraph [0038]. Several of the dependent claims are amended for consistency with the amended independent claims.

New claims 51, 52, and 53, which depend directly from independent claims 1, 23 and 30 respectively, are introduced. These new claims recite that an abdominal pressure of the patient is measured, and that application of the negative pressure to the patient's ribcage and/or abdomen is further controlled in response to the measured abdominal pressure of the patient. Support for new claims 51, 52, and 53 is found in the disclosure as originally filed, for example at paragraph [0039].

Some spelling or similar other clerical errors are also corrected in dependent claims 17, 33, 40, and 50.

No new matter is believed to be introduced in the present application by way of the present amendment.

Therefore, claim 1 as amended recites a method of delivering combined positive and negative pressure assist ventilation to a patient. Neural inspiratory activation of the patient is detected. A positive pressure is applied to the patient's airways while a negative pressure is applied around the patient's ribcage and/or abdomen. Control of application of the positive and negative pressures is made in response to the neural inspiratory activation, with a level of the

positive pressure being controlled as a function of the detected neural inspiratory activation. Independent claims 23 and 30 have a similar scope.

Claim rejections under 35 U.S.C. § 103

In the Final Office Action, claims 1-17, 23-30, 32-34, 36-38, 40, 41 and 43-45 were rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Bennett (US 2,648,331) in view of Sinderby (US 5,820,560).

In the Final Office Action, claims 4 and 25, whose subject matter is now incorporated in the amended claims 1, 23 and 30, were deemed unpatentable over Bennett in view of Sinderby. Applicants respectfully traverse this rejection for the following reasons.

Bennett discloses the supplementation of normal respiratory action of a standard respirator having a main bellows 16 by supplying intermittent positive pressure internally from an auxiliary bellows 56, so as to inflate the patient's lungs (column 1, lines 48-52). Bennett also describes that the intermittent positive pressure is provided in proper synchronism with the standard respirator (column 2, lines 13-16). Column 4, lines 35-41 of Bennett finally indicates that the magnitude of both the positive and negative pressures is determined simultaneously by the positioning of a crosshead 34 upon a lever 21, the crosshead 34 being held in position by use of a locking screw operated by a hand grip 36. Maximum positive pressure is set at a pressure control box 52, in which a lever 189 is used to manually adjust a pin 187 that controls the tension of a spring 186, the spring 186 being part of a relief valve 181 that limits the maximum positive pressure (column 9, lines 24-50). The speed of a driving motor 26, whose action is transmitted to the lever 21 via a belt 28, a set of speed reduction gears within a gearbox 29, a driven shaft 31, a crank 32 and a connecting rod 33, controls the frequency of the respiratory cycles. Compression of the two bellows 16 and 56 is effected through movement of the same lever 21, as clearly seen in Fig. 10.

Sinderby describes detecting an electromyographic (EMG) signal of the patient's diaphragm to control operation of a lung ventilator, for example a positive pressure lung ventilator. More specifically, Sinderby describes detecting the EMG signal to control operation of a single ventilator, in particular a positive pressure ventilator.

It is respectfully submitted that Bennett cannot be modified to use Sinderby's EMG signal to teach a step of "controlling application of the positive and negative pressures in response to the detected neural inspiratory activation of the patient", Bennett also cannot be modified to teach "controlling a level of the positive pressure applied to the patient's airways as a function of the detected neural inspiratory activation of the patient". Such modifications to Bennett would require inventive ingenuity.

Bennett and Sinderby cannot be readily combined by those of ordinary skill in the art, without the use of inventive ingenuity, to arrive at the subject matter as recited in the amended, independent claims.

The respirator of Bennett cannot be "controlled" in the sense of "controlling... in response to the detected neural inspiratory activation of the patient" or in the sense of "controlling... as a function of the detected neural inspiratory activation" as set forth in the present claim 1. The adjustment of the magnitude of the ventilatory assist provided by the respirator of Bennett is purely manual and mechanical. Integration of the EMG signal of Sinderby to control the level of ventilatory assist (positive pressure) would require a complete change of the structure of Bennett's respirator, beyond the reach of those of ordinary skill in the art. More specifically, Bennett's crosshead 34, lever 21 and handgrip 36 and/or lever 189 would need to be replaced with entirely different and distinct elements to actuate the bellows 16 and 56 and/or to adjust the pressure control box 52 in response to an EMG signal in view of controlling the level of the positive pressure. Replacement of the manual and mechanical devices of Bennett with a new structure capable of acting upon an EMG signal would amount to an invention.

In section 17 Response to Arguments of the Final Office Action, the Examiner states that "Applicant's argument that combination of Bennett and Sinderby fail to teach that the control of positive and negative pressures is based on a neural inspiratory signal is not persuasive because Bennett teaches the synchronization of applying positive and negative pressures and Sinderby teaches the use of neural inspiratory signals to control the application of positive pressure, therefore the combination of Bennett and Sinderby teach the control of both the applied positive and negative pressures being based on neural inspiratory signals since the application of both is synchronized". Applicant respectfully disagrees.

A combination of Bennett with Sinderby, without a structural change in Bennett, does not provide a necessary enablement to arrive at the present invention as claimed. One of ordinary skill in the art would not be capable, without the exercise of inventive ingenuity, to make or use the invention of claim 1 from a reading of Bennett and of Sinderby. Without such enablement, the person of ordinary skill in the art having been exposed to Bennett and Sinderby would not have been able to combine these references. This combination can only be made using impermissible hindsight. From the MPEP 2142: "Knowledge of applicant's disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the 'differences,' conduct the search and evaluate the 'subject matter as a whole' of the invention. The tendency to resort to 'hindsight' based upon applicant's disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art" (emphasis added). Neither Bennett nor Sinderby teach a manner of integrating an EMG signal into Bennett's mechanical respirator.

Accordingly, those of ordinary skill in the art would find in Bennett no motivation and no enablement to use the teaching of Sinderby to control either (a) triggering and termination or the application of the positive and negative pressures and (b) the level of the positive pressure in relation an EMG signal as provided by Sinderby. The manual and mechanical adjustment structure taught by Bennett is designed for producing a positive pressure of constant level applied at a constant rate and is neither suitable nor adaptable for automatically adjusting a level and rate of application of such positive pressure in response to an EMG or other signal.

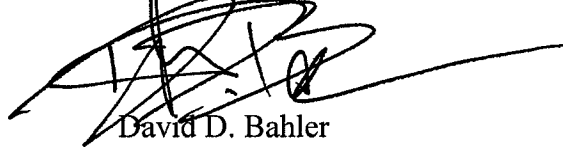
Summarizing, a combination of Bennett with Sinderby, does not teach adjusting a rate of application and a level of positive and negative pressures as a function of a detected neural inspiratory activation, within a system or method for delivering combined positive and negative pressure assist ventilation.

At least for the above reasons, it is respectfully submitted that the combination of Bennett and Sinderby does not render amended independent claims 1, 23 and 30 as amended obvious.

Since the remaining dependent claims are each dependent upon one of the above mentioned independent claims, which are believed to contain patentable subject matter, these dependent claims are also believed to be allowable in the present patent application.

In view of the above amendments and remarks, the applicant respectfully requests favorable reconsideration of the present application.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'David D. Bahler', with a long horizontal flourish extending to the right.

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